

NOV 12 2003

K033066
510(k) Summary
for
XiScan 4000 Imaging System

1. SPONSOR

XiTec Holdings LLC
4 New Park Road
East Windsor, CT 06088

Contact Person: Mr. Steven Hanright
Telephone: 860-292-7055

Date Prepared: September 26, 2003

2. DEVICE NAME

Proprietary Name: XiScan 4000 Transportable Imaging System
Common/Usual Name: Fluoroscopic mini C-arm systems
Classification Name: Image-intensified fluoroscopic X-ray system

3. PREDICATE DEVICE

XiScan 6000 Imaging System (K003568)

4. INTENDED USE

The XiScan 4000 Transportable Imaging System is intended for fluoroscopic imaging of patient extremities.

5. DEVICE DESCRIPTION

The XiScan 4000 Transportable Imaging System is a compact, mobile, mini C-arm system specifically designed for fluoroscopic imaging of patient extremities. The XiScan 4000 Imaging System can be operated in either manual or automatic exposure rate control (AERC) modes, with options of reduced radiation LOW DOSE and high resolution STANDARD DOSE when using AERC. The XiScan 4000 offers a range of functions for image manipulations. It features touchscreen controls to manage on-screen patient information and image storage.

K033066

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The XiScan 4000 Transportable Imaging System has the same intended use, and similar technical specifications, as compared to the predicate device. Both devices are mobile mini C-arm systems with similar technique factors, SIDs, field-of-view sizes, and image enhancement options. A bench test comparison of the devices confirmed that the patient X-ray exposure rates for imaging various anatomies are similar. Based on these comparisons, the XiScan 4000 Transportable Imaging System is substantially equivalent to the XiScan 6000 Imaging System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Xitec Holding, LLC
% Mr. Daniel J. Dillion, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K033066
Trade/Device Name: XiScan 4000
Transportable Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified
fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 JAA
Dated: October 22, 2003
Received: October 23, 2003

Dear Mr. Dillion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

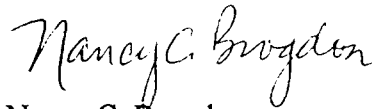
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033066

Device Name: XiScan 4000 Transportable Imaging System

Indications For Use:

The XiScan 4000 Transportable Imaging System is intended for fluoroscopic imaging of patient extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033066

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)